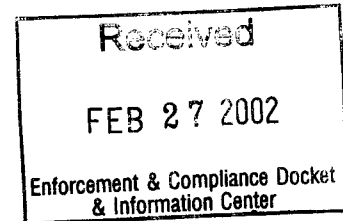


National Alliance of Independent Crop Consultants

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Allison Jones, Executive Vice President

27 February 2002

U.S. Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW
Washington, DC 20460



Re: National Alliance of Independent Crop Consultants (NAICC) CROMERRR
Response Document/Docket Number EC-2000-007

Introduction

The National Alliance of Independent Crop Consultants (NAICC) is pleased to submit comments on the Environmental Protection Agency's proposed Cross-Media Electronic Reporting and Records Rule (CROMERRR), which was published in the 66 Federal Register 46162 (31 August 2001). The NAICC represents the majority of the Contract Researchers conducting field studies under Good Laboratory Practice (GLP) regulations to provide support data for pesticide registrations under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) 40 CFR Part 160. These specialized field studies include but are not limited to magnitude of residue, efficacy, worker exposure, soil dissipation, groundwater and other environmental fate studies. This work is performed on a contractual basis for those multi-national corporations and domestic entities seeking an EPA registration to market pesticides in the United States. Contract Researchers are subject to various Federal, State and Local regulations, in addition to enforcement provided under FIFRA 40 CFR Part 160.17 for non-compliance.

A. The Proposed Rule is Not Voluntary

In the course of conducting these studies, contract researchers capture, maintain, modify, archive, retrieve and transmit study critical data electronically in many ways and for many purposes. For example, remote data loggers and weather stations are used to record environmental conditions at field test locations, test substance storage areas and for sample held in storage prior to shipment for analysis. Some of the data collected are summarized using spreadsheets or other proprietary software. Word processing, database, and spreadsheet software is used to create and maintain organizational charts, master schedules, curriculum vitae, training records, SOPs, and field plot histories along with other facility data required to maintain Part 160 compliance.

In recent years many clients have moved forward with some form of electronic raw data capture and management at the field level and the transmission of that electronic

information for incorporation into their database as the study progresses. Certain GLP clients require Contract Researchers to use customized software, referred to as electronic notebooks, to capture some or all of the raw data electronically in real time. At the completion of the study this electronic notebook is transferred to the client via email or on a disc. Study directors and field contractors also communicate throughout the course of a study using email.

The collection, maintenance and modification of data in electronic format is pervasive in our industry. As proposed CROMERRR is not a voluntary rule for Contract Researchers and should the rule be implemented, compliance would be a prerequisite to conducting studies that meet the requirements of FIFRA 40 CFR Part 160.

B. The Proposed Rule Creates Requirements That Would Impose Significant Cost and in Some Cases are Impractical

This specialized group of Contract Researchers is comprised exclusively of independent privately owned small businesses, many operating as sole proprietorships. Nationally less than 150 of these firms provide GLP compliant field studies. To assess the size of these organizations that would be required to comply with CROMERRR, a survey of the NAICC Researcher Membership was conducted to compare the year 1999 to the year 2001. Approximately 25% of the Contract Research Members responded. Survey results showed that during 1999 an average of 18.4 studies per site were conducted providing a gross income of \$134,000 and in 2001 the average number of trials per contractor had declined to 15.4 with a gross value of \$110,000. The data shows that due to consolidation in the Agrochemical industry and movement toward transgenic technologies for plant protection, there has been a reduction in the number of new chemical products in development and hence a declining number of GLP Field studies. At this early date all indications suggest a continuation of this trend in 2002.

Considering the low gross values involved in conducting FIFRA compliant studies, contract research organizations will not be able to absorb the EPA estimate expenditure of \$40,000 per location to bring a facility into compliance with CROMERRR, considered to be a conservative cost estimate by many. In addition there would be a significant cost to maintain CROMERRR compliant systems over time.

In order to assure CROMERRR compliance, a facility would need to dedicate a computer literate individual to that task. Our survey also indicated that in 2001 the smallest Contract Research Facility consisted of one individual conducting a single trial for \$6,000. The largest Facility conducted 26 trials valued at \$320,000 involving 9 personal in the completion of those GLP compliant studies. Assigning a computer literate individual solely to the task of assuring that a facility is CROMERRR compliant would be beyond the financial means of these organizations. Simple business math clearly documents the onerous financial impact CROMERRR would place on Contract Researchers and it is likely that even the largest Organizations providing GLP field studies could not justify the cost of CROMERRR compliance.

Ironically the ability to satisfy EPA mandated geographical distribution for studies supporting pesticide registrations is dependant on the existence of small contractors located in areas representative of the wide range of environmental zones and cropping regions in the US. Implementation of CROMERRR would seriously disrupt the current system of GLP Research Facilities leaving many regions without suitable locations to

conduct GLP compliant studies. The EPA requirement that records supporting pesticide registrations are retained for the life of the product, often 30 to 50 years, is an additional financial burden due to the costs associated with archiving and migrating electronic record over time. Electronic archiving technology is not developed to the point where it would be cost effective for organizations the size of Contract Researchers to maintain electronic archives through the constantly changing technology in hardware and software.

It is the contention of the NAICC that consideration for the financial impact of this rule on small businesses such as Contract Researchers is seriously deficient and support of any claimed benefits is lacking. Implementation of the rule would result in a significant loss of facilities capable of providing the GLP compliant data required under FIFRA. It is that very data that allow EPA to meet its mandate and make informed and accurate decisions on the environmental and worker safety issues associated with pesticides.

C. CROMERRR Creates Conditions Unfavorable to Adoption of Electronic Technology, Contrary to the Intent of The Government Paper Elimination Act

In view of the fact that the Paper Reduction Act provides the basis for CROMERRR, we have not been able to identify any gains in efficiency under this rule. Considering the added cost involved to bring a facility into compliance with CROMERRR, most of our members and other small groups would be forced to revert certain or all record keeping to paper as opposed to using an electronic format. In contrast with the original intent of the Paper Reduction Act, CROMERRR would have the effect of actually increasing the use of paper in small organizations due to the high cost of compliance versus the potential return. Since the adoption of GLP guidelines under FIFRA for EPA studies a variety of electronic technologies have been incorporated into the data collection and record keeping process adding both efficiency and accuracy. Implementation of CROMERRR would require most of our members to abandon the use of this technology for older methods that are GLP compliant but sacrifice accuracy and convenience.

Conclusions

The NAICC is concerned with the onerous cost the proposed CROMERRR would impose and the impact of those costs on small businesses. We believe the economic analysis supporting this rule is woefully lacking and net benefits would not be realized in practice. Implementation of the rule as proposed would make the use of electronic data capture and management in small businesses impractical and promote return to paper systems. It is likely CROMERRR would prevent the majority of Contract Researchers from continued production of data for submission to EPA in support of the decision making process under FIFRA. It is obvious that there is no simple set of modification that can rectify the many concerns being expressed by the regulated community. Therefore the NAICC believes that at a minimum the record-keeping portion of the proposed rule should be withdrawn for reevaluation. We would be pleased to participate in any such reevaluation to assist EPA in their efforts to develop a system that would make compliance feasible at our level and address your electronic record keeping concerns.

National Alliance of Independent Crop Consultants (NAICC) CROMERRR Response Document/Docket Number EC-2000-007

Executive Summary

The National Alliance of Independent Crop Consultants (NAICC) welcomes the opportunity to comment on the Cross-Media Electronic and Record-Keeping Reporting Rule (CROMERRR) published in the 66 Federal Register 46162 (31 August 2001). Within the NAICC membership are individuals providing Contract Research Services to clients who submit those data to the Environmental Protection Agency in support of pesticide registrations under the Federal Insecticide and Rodenticide Act (FIFRA). As our membership would be subject to compliance with the record-keeping portion of the proposed rule, we have restricted comments to that section, especially as it would affect Contract Researchers as small businesses. Although there are numerous aspects of the record-keeping section that would affect us, our comments deal with those portions having the greatest impact on small businesses that rely heavily on electronic technology in their day-to-day operation. We note that our colleagues at the American Chemistry Council (ACC) and Society of Quality Assurance (SQA) have address the broader range of concerns shared with the entire regulated community and we support those Comment Documents.

Contract Researchers have provided data in a regulated environment since 1989, supplying data for submission to EPA under FIFRA and in compliance with Good Laboratory Practices (GLP) 40 CFR Part 160. This regulated environment includes enforcement under the Laboratory Integrity Branch of the Office of the Office of Enforcement and Compliance Assurance (OECA). Our members certainly understand the benefits electronic data collection and record keeping can provide for improved accuracy and efficiency. Unfortunately we do not feel the proposed CROMERRR would allow us to fully utilize electronic technology and achieve the potential gains in either of those areas. Concerns expressed by by our members and others who would be regulated by the proposed CROMERRR demonstrate that the modifications needed to make the rule functional would be complicated and extensive. Fully recognizing the importance of a rule providing oversight for electronic record keeping we must respectfully recommend that at a minimum the record keeping provisions of the proposed CROMERRR be withdrawn as the most logical approach at this point.

We believe our recommendation for withdrawal is justified for the following reasons as provided in our attached Comment Document:

- The Rule is not voluntary considering the extensive use of electronic data collection and management already established in the collection of data for submission to EPA.
- The Proposed Rule Creates Requirements That Would Impose Significant Cost and in Some Cases are Impractical.
- CROMERRR Creates Conditions Unfavorable to Adoption of Electronic Technology, Contrary to the Intent of The Government Paper Elimination Act

NAICC would be pleased to collaborate with EPA as a stakeholder to develop a system that would make compliance feasible at our level and address your electronic record keeping concerns. We look forward to your final decision and appreciate your consideration of our concerns with the proposed rule and EPA's effort to understand the impact implementation would have on Contract Researchers and other small organizations that would be regulated by this action.

Respectively Submitted,

A handwritten signature in black ink that reads "Allison Jones". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Allison Jones, Executive Vice President
National Alliance of Independent Crop Consultants



JonesNAICC@aol.co
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02/27/02 04:22 PM

To: docket.oeca@epamail.epa.gov
cc: LABS@labservices.com (Jim Steffel)
Subject: Docket Number EC-2000-007

Attached is a response document to Docket Number EC-2000-007 submitted by the National Alliance of Independent Crop Consultants (NAICC).

Three copies of the original NAICC document (with original signatures) are being sent via FedEx.

Thank you for the opportunity to submit these comments. If you have any questions, or need additional information, please do not hesitate to contact me.

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